

CLAIMS

1. A method for differentiating between two states of an analyte that exists in a plurality of forms, which states differ from one another in the nature and/or amount of one or more forms present therein, wherein:
  - a) at least two contemporaneous assays are conducted, the first of which has a specificity for the analyte that is essentially constant irrespective of whether the analyte is in one form or the other, and the second of which has a specificity for the analyte that differs depending on which form the analyte is in; and
  - b) the results of the first and second assays are compared.
2. A method of testing for the existence of a menopausal condition in a human female by means of a gonadotrophin assay, wherein:
  - a) at least two contemporaneous assays are conducted, the first of which has a specificity for the gonadotrophin that is essentially constant irrespective of whether the human female is pre-menopausal or post-menopausal, and the second of which has a specificity for the gonadotrophin that differs depending on whether the human female is pre-menopausal or post-menopausal; and
  - b) the results of the first and second assays are compared.

3. A method according to claim 1, wherein the analyte is a gonadotrophin.

4. A method according to claim 2 or 3, wherein the gonadotrophin is follicle stimulating hormone (FSH).

5. A method according to any one of the preceding claims, wherein both contemporaneous assays are sandwich-format assays. *(MD)*

6. A method, according to any one of claims 2-5, wherein each of said at least two contemporaneous assays uses an antibody pair directed against the alpha and beta peptide chains of the gonadotrophin, but both members of the antibody pair in the first assay differ from the members of the antibody pair in the second assay.

7. A method according to any one of the preceding claims, wherein each assay provides a quantitative result, and the ratio of the two results is taken as indicative of menopausal status.

8. A method according to any one of the preceding claims, wherein the at least two contemporaneous assays are repeated at intervals of at least one week to determine whether the menopausal status is changing.

9. A method according to claim 8, wherein the human subject is one undergoing a course of HRT.

10. An assay device for testing a body fluid sample obtained from a human female, the device having a first analyte-responsive (preferably gonadotrophin-responsive) signal-

producing means that provides a readable signal that, relative to a reference standard, is constant irrespective of whether the sample is derived from a pre-menopausal or post-menopausal subject, and a second analyte-responsive (preferably gonadotrophin-responsive) signal-producing means that provides a readable signal that, relative to a reference standard, differs depending on whether the sample is derived from a pre-menopausal or post-menopausal subject.

11. An assay device according to claim 10, wherein the gonadotrophin is FSH.
12. An assay device according to claim 10 or claim 11, wherein each readable signal is caused by the binding in a detection zone of a specific binding agent labelled with a particulate direct label.
13. A method according to claim 1, or an assay device according to claim 10, substantially as hereinbefore described.
14. A method according to claim 4, or an assay device according to claim 11, wherein the first assay, or first gonadotrophin-responsive signal-producing means, as appropriate, uses a pair of anti-FSH antibodies that detect "total" FSH.
15. An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00032004.
16. An anti-FSH monoclonal antibody as expressed by hybridoma cell line ECACC 00032005.

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17. A method according to claim 4, or an assay device according to claim 11, wherein the second assay uses either or both of the anti-FSH antibodies claimed in claims 15 and/or 16.